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| 10/627,367 | 07/24/2003 | Leon Axel | 5986/1K435US1 | 2452 |

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| EXAMINER |
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ALTER, ALYSSA M

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| ART UNIT | PAPER NUMBER |
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3762

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06/04/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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| Office Action Summary | Application No. 10/627,367 | Applicant(s) AXEL, LEON | |
| | Examiner Alyssa M. Alter | Art Unit 3762 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 and 28-55 is/are pending in the application.
4a) Of the above claim(s) 48-55 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-26 and 28-47 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 48-55 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 August 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>8/16/06</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restrictions

Newly submitted claims 48-55 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: correlating to at least one of a P-wave and T-wave within the ECG.

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions correlate either the QRS complex or the P-wave and T-wave.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 48-55 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Response to Arguments

Applicant's arguments with respect to claims 1-39 have been considered but are moot in view of the new ground(s) of rejection necessitated by amendment under Long (US 4,884,345), Bjorling et al. (US Patent Publication 20030100923 A1) and Blakeley et al. (US 5,038,785) as described below.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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1. Claims 25-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear if claims 25 and 26 are independent or dependent claims. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 1-9, 16-22, 28 and 30-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Long (US 4,884,345). Long discloses an adjustable template for ECG analysis. Wherein the adjustable template device has a transparent window for placement or superimposing over an ECG trace.

2. Claims 1-9, 16-22, 25-26, 28 and 30-33 are rejected under 35 U.S.C. 102(e) as being anticipated by Bjorling et al. (US Patent Publication 20030100923 A1). Bjorling et al. depicts in figure 5, a QRS detector, template collector and a pattern recognition unit. The ECG morphology is correlated to the template morphology with direct correspondence between detected signals and stored templates.

As Bjorling et al. discloses on page 1, paragraph 10, "conventional detection algorithms analyze the signal by undertaking one or more threshold comparisons and/or by analyzing the rate of occurrence of a particular characteristic of the signal (i.e., maxima, minima, zero crossings, etc.) over a given period of time. Comparison of the signal waveform to stored signal templates, respectively representing previously-obtained abnormal signals, is also a known technique. In this manner, a determination is made as to whether the incoming signal represents normal sinus rhythm, a PVC, tachycardia, atrial fibrillation, ventricular fibrillation, etc".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 1-5, 7-11, 16-26, 28-32, 34-35, 40-41 and 44-45 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Blakeley et al. (US 5,038,785). Blakeley et al. discloses a cardiac monitor to record cardiac signals during a MRI scan. Blakeley also discloses "the threshold detector 78 establishes a threshold level at two thirds of the previous R-wave peak derivative. Once the threshold has been exceeded a zero cross means 80 searches for the next occurrence of zero crossing of the derivative signal. Comparing the derivative of the received cardiac signal with two thirds of the previous R-wave peak derivative locates

the R-wave peak of the current cardiac signal. In this manner, variations in the derivative of the cardiac signals are automatically corrected"(col. 6, lines 54-63).

Furthermore, Blakeley discloses a comparing means, which "compares the first electrical signal with a preselected signal property" (col. 2, lines 26-27). Since the electrical signals are compared with preselected signal property there would necessarily be a template employed in the comparison.

In the alternative, although the examiner considers Blakeley et al. to disclose a template above, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the compared signals as taught by Blakeley et al. with the a template, since it is well known in the art to employ templates as a means to quickly and accurately compare cardiac signal morphology to diagnosis patient cardiac health.

2. Claims 6, 12-15, 33, 36-39 and 42-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blakeley et al. (US 5,038,785). Blakeley et al. discloses the claimed invention except for the assigned correlation value or the assigned weighted score. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the correlation to the ECG template as taught by Blakeley et al. with a value or weighted score, in order to accurately correlate the features of the signal to the template. Furthermore, the numerical score would enable a patient ECG to be monitored for arrhythmias, as disclosed by Blakeley et al.

3. Claims 12-15, 33 and 36-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bjorling et al. (US Patent Publication 20030100923 A1). Bjorling et al.

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discloses the claimed invention except for the assigned weighted score. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the correlation to the ECG template as taught by Bjorling et al. with a value or weighted score, in order to accurately correlate the features of the signal to the template.

4. Claims 12-15, 33 and 36-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Long (US 4,884,345). Long discloses the claimed invention except for the assigned weighted score. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the correlation to the ECG template as taught by Long with a value or weighted score, in order to accurately correlate the features of the signal to the template.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

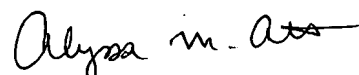
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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alyssa M. Alter whose telephone number is (571) 272-4939. The examiner can normally be reached on M-F 9am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Alyssa M Alter
Examiner
Art Unit 3762


GEORGE R. EVANISKO
PRIMARY EXAMINER
5/29/11